# General

## Guideline Title

Behavioral counseling to promote a healthful diet and physical activity for cardiovascular disease prevention in adults with cardiovascular risk factors: U.S. Preventive Services Task Force recommendation statement.

## Bibliographic Source(s)

U.S. Preventive Services Task Force. Behavioral counseling to promote a healthful diet and physical activity for cardiovascular disease prevention in adults with cardiovascular risk factors: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2014 Oct 21;161(8):587-93. [21 references] PubMed

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Behavioral counseling in primary care to promote a healthy diet: recommendations and rationale. Am J Prev Med. 2003 Jan;24(1):93-100. [54 references]

This guideline meets NGC's 2013(revised) inclusion criteria.

# Recommendations

## Major Recommendations

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the levels of certainty regarding net benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

Summary of Recommendation and Evidence

The USPSTF recommends offering or referring adults who are overweight or obese and have additional cardiovascular disease (CVD) risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention. (B recommendation)

Clinical Considerations

Patient Population Under Consideration

This recommendation applies to adults aged 18 years or older in primary care settings who are overweight

or obese and have known CVD risk factors (hypertension, dyslipidemia, impaired fasting glucose, or metabolic syndrome). In the studies reviewed by the USPSTF, a substantial majority of participants had a body mass index (BMI) greater than 25 kg/$m^2$.

Behavioral Counseling Interventions

Most studies evaluated interventions that combined counseling on a healthful diet and physical activity and were intensive, with multiple contacts (which may have included individual or group counseling sessions) over extended periods. Interventions involved an average of 5 to 16 contacts over 9 to 12 months depending on their intensity. Most of the sessions were in-person, and many included additional telephone contacts. Interventions generally focused on behavior change, and all included didactic education plus additional support. Most included audit and feedback, problem-solving skills, and individualized care plans. Some trials also focused on medication adherence. Interventions were delivered by specially trained professionals, including dietitians or nutritionists, physiotherapists or exercise professionals, health educators, and psychologists.

Many types of intensive counseling interventions were effective. However, it was not clear how the magnitude of the effect was related to the format of the intervention (for example, face-to-face, individual, group, or telephone), the person providing the counseling, the duration of the intervention, or the number of sessions because different combinations of components were effective (see the Implementation section in the original guideline document for more information on effective interventions). Because of the intensity and expertise required, most interventions were referred from primary care and delivered outside that setting.

Other Approaches to Prevention

Tobacco use continues to be one of the most important risk factors for CVD. Helping patients with tobacco cessation is a critical component of CVD prevention. The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions to those who use such products. The U.S. Public Health Service has published guidelines to further help clinicians.

Multifaceted approaches with linkages between primary care practices and community resources could increase the effectiveness of interventions. Effective interactions between health care and community interventions, specifically public health and health policy interventions (such as healthy community design and built environment), can support and enhance the effectiveness of clinical interventions (more information is available at www.cdc.gov/healthyplaces ). The Community Preventive Services Task Force recommends several community-based interventions to promote physical activity, including community-wide campaigns, social support interventions, school-based physical education, and environmental and policy approaches. It also recommends programs promoting diet and physical activity for persons who are at increased risk for type 2 diabetes on the basis of strong evidence of the effectiveness of these programs in reducing the incidence of new-onset diabetes. These recommendations are available at www.thecommunityguide.org .

The Million Hearts initiative (http://millionhearts.hhs.gov ) aims to decrease the number of heart attacks and strokes by 1 million by 2017. It emphasizes the use of effective clinical preventive services combined with multifaceted community prevention strategies.

In 2010, the U.S. Department of Agriculture and the U.S. Department of Health and Human Services jointly issued the "Dietary Guidelines for Americans." The latter also issued complementary physical activity guidelines.

Useful Resources

The USPSTF has a wide range of recommendations focusing on CVD prevention. The current recommendation focuses on behavioral counseling that encourages healthy eating and physical activity behaviors to improve cardiovascular health. It does not address weight-loss programs. The USPSTF recommends that clinicians selectively initiate behavioral counseling to promote a healthful diet and physical activity in patients who are not obese and not at increased cardiovascular risk. The USPSTF does

not address behavioral counseling in patients with a BMI less than 25 kg/$m^2$ who are at increased risk for CVD. However, for patients with a BMI of 30 kg/$m^2$ or greater, the USPSTF recommends screening these patients for obesity and offering or referring them to intensive, multicomponent behavioral counseling for weight loss.

In another recommendation, the USPSTF recommends screening for lipid disorders in adults according to age and risk factors. It also recommends screening for high blood pressure in adults, screening for diabetes in patients with elevated blood pressure, and aspirin use when appropriate. These recommendations are available at www.uspreventiveservicestaskforce.org .

Definitions:

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

| Grade | Grade Definitions | Suggestions for Practice |
|---|---|---|
| A | The USPSTF recommends the service. There is high certainty that the net benefit is substantial. | Offer/provide this service. |
| B | The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. | Offer/provide this service. |
| C | The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small. | Offer/provide this service for selected patients depending on individual circumstances. |
| D | The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. | Discourage the use of this service. |
| I Statement | The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined. | Read the "Clinical Considerations" section of USPSTF Recommendation Statement (see the "Major Recommendations" field). If this service is offered, patients should understand the uncertainty about the balance of benefits and harms. |

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

| Level of Certainty | Description |
|---|---|
| High | The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies. |
| Moderate | The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:<br><br>The number, size, or quality of individual studies<br>Inconsistency of findings across individual studies<br>Limited generalizability of findings to routine primary care practice<br>Lack of coherence in the chain of evidence |

| Level of Certainty | Description |
| --- | --- |
| | As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion. |
| Low | The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:<br><br>The limited number or size of studies<br>Important flaws in study design or methods<br>Inconsistency of findings across individual studies<br>Gaps in the chain of evidence<br>Findings not generalizable to routine primary care practice<br>A lack of information on important health outcomes<br><br>More information may allow an estimation of effects on health outcomes |

## Clinical Algorithm(s)

None provided

# Scope

## Disease/Condition(s)

Cardiovascular disease (CVD)

## Guideline Category

Counseling

Prevention

## Clinical Specialty

Cardiology

Family Practice

Internal Medicine

Nursing

Nutrition

Preventive Medicine

## Intended Users

Advanced Practice Nurses

Allied Health Personnel

Dietitians

Nurses

Physician Assistants

Physicians

Public Health Departments

## Guideline Objective(s)

To summarize the current U.S. Preventive Services Task Force (USPSTF) recommendations and supporting evidence on primary care-relevant counseling interventions to promote cardiovascular disease (CVD) prevention

## Target Population

Adult aged 18 years or older in primary care settings who are overweight or obese and have known cardiovascular disease (CVD) risk factors

## Interventions and Practices Considered

Intensive behavioral counseling interventions to promote a healthful diet and physical activity

## Major Outcomes Considered

Key Question 1: Do primary care–relevant behavioral counseling interventions for physical activity and/or healthy diet improve cardiovascular disease (CVD) health outcomes (e.g., prevent morbidity and mortality) in adults with known CVD risk factors (e.g., hypertension, dyslipidemia, impaired fasting glucose, metabolic syndrome)?

> Are there population or intervention characteristics that influence the effectiveness of the interventions?

Key Question 2: Do primary care–relevant behavioral counseling interventions for physical activity and/or healthy diet improve intermediate outcomes associated with CVD (e.g., blood pressure, lipids, glucose, weight) in adults with known CVD risk factors (e.g., hypertension, dyslipidemia, impaired fasting glucose, metabolic syndrome)?

> Are there population or intervention characteristics that influence the effectiveness of the interventions?

Key Question 3: Do primary care–relevant behavioral counseling interventions for physical activity and/or healthy diet change associated health behaviors in adults with known CVD risk factors (e.g., hypertension, dyslipidemia, impaired fasting glucose, metabolic syndrome)?

> Are there population or intervention characteristics that influence the effectiveness of the interventions?

Key Question 4: What are the adverse effects of primary care–relevant behavioral counseling interventions for physical activity and/or healthy diet in adults with known CVD risk factors (e.g., hypertension, dyslipidemia, impaired fasting glucose, metabolic syndrome)?

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Kaiser Permanente Research Affiliates Evidence-based Practice Center (EPC) for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Data Sources and Searches

EPC staff searched MEDLINE, PubMed, PsycINFO, the Database of Abstracts of Reviews of Effects, and the Cochrane Central Register of Controlled Trials from January 2001 to October 2013. EPC staff supplemented searches with suggestions from experts and reference lists from other relevant systematic reviews.

Study Selection

Two investigators independently reviewed 7218 abstracts and 553 full-text articles against a priori–specified inclusion criteria (see Appendix A Figure 1 in the evidence report [see the "Availability of Companion Documents" field]). They included studies in adults who had at least 1 cardiovascular risk factor, including hypertension, dyslipidemia, impaired fasting glucose or glucose tolerance, metabolic syndrome, and cigarette smoking. EPC staff excluded studies limited to persons with known diabetes (considered a cardiovascular disease [CVD] risk equivalent), coronary artery disease, cerebrovascular disease, peripheral artery disease, or severe chronic kidney disease. They also excluded populations at increased risk for CVD (such as those who are obese, physically inactive, and prehypertensive) but without other CVD risk factors because these bodies of evidence were considered in previous reviews and USPSTF recommendations. EPC staff included behaviorally based counseling interventions to promote a healthy diet or physical activity, delivered alone or as part of a multicomponent intervention. They excluded interventions that provided controlled diets or supervised exercise, as opposed to interventions aimed at evaluating whether counseling could change behavior.

EPC staff limited studies of efficacy or effectiveness to fair- or good-quality randomized, controlled trials or controlled clinical trials that had at least 6 months of follow-up, were done in developed countries, and published their results in 1990 or later. Included trials had to have a control group (such as usual care, a minimal intervention, or attention control). They examined health outcomes (such as morbidity or mortality related to CVD), intermediate health outcomes (such as physiological measures of blood pressure, lipid and glucose, and weight; diabetes incidence; medication use; and composite CVD risk scores), and behavioral outcomes (such as self-reported dietary intake and physical activity or objectively measured markers of behavior change [such as $VO_2$max or urinary sodium]). EPC staff also included observational studies that reported serious harms (that is, adverse events resulting in unexpected or unwanted medical attention).

## Number of Source Documents

- Key Question 1 (Health Outcomes): 16 studies in 51 unique publications
- Key Question 2 (Intermediate Health Outcomes): 71 studies in 160 unique publications
- Key Question 3 (Health Behaviors): 61 studies in 144 unique publications
- Key Question 4 (Harms): 10 studies in 37 unique publications

## Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Articles that met the inclusion criteria were critically appraised by two reviewers independently using the U.S. Preventive Services Task Force (USPSTF) and National Institute for Health and Care Excellence criteria. They rated articles as good-, fair-, or poor-quality.

Good-quality studies generally met all criteria, whereas fair-quality studies did not meet all criteria but had no known important limitation that could invalidate its results. Poor-quality studies had important limitations that were considered fatal flaws (for example, they had greater than 40% attrition with or without differential attrition between intervention groups; a lack of randomization with biased assignment of participants to intervention groups, often with differences in baseline characteristics or no reporting of baseline characteristics; per-protocol analyses only; and very did not allow for adequate assessment of quality); thus, they were excluded from this review.

## Methods Used to Analyze the Evidence

Meta-Analysis of Randomized Controlled Trials

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Kaiser Permanente Research Affiliates Evidence-based Practice Center (EPC) for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Data Extraction and Quality Assessment

One reviewer extracted population characteristics, study design elements, intervention and control characteristics, and study results into standardized evidence tables. A second reviewer checked the data for accuracy. Articles that met the inclusion criteria were critically appraised by 2 reviewers independently using the USPSTF and National Institute for Health and Care Excellence criteria.

EPC reviewers rated articles as good-, fair-, or poor-quality. Good-quality studies generally met all criteria, whereas fair-quality studies did not meet all criteria but had no known important limitation that could invalidate its results. Poor-quality studies had important limitations that were considered fatal flaws (for example, more than 40% attrition with or without differential attrition between intervention groups; lack of randomization with biased assignment of participants to intervention groups, often with differences in baseline characteristics or no reporting of baseline characteristics; per protocol analyses only; and very poor reporting about description of methods, which did not allow adequate assessment of quality); thus these studies were excluded from this review.

Data Synthesis and Analysis

Because of the clinical heterogeneity across this body of evidence, EPC reviewers stratified the analyses according to the type of intervention (that is, a focus on dietary counseling alone, physical activity alone, or combined diet and physical activity counseling) and according to how study populations were targeted or defined (that is, dyslipidemia, hypertension, impaired fasting glucose or glucose tolerance, or mixed risk factors). They did random-effects meta-analyses for 5 or more studies using the DerSimonian-Laird method to estimate the effect size of counseling on intermediate health outcomes (that is, systolic and

diastolic blood pressure; total, high-density lipoprotein, and low-density lipoprotein cholesterol; triglycerides; fasting blood glucose; diabetes incidence; and weight or body mass index). EPC reviewers did qualitative synthesis for health outcomes, behavioral outcomes, and harms. Outcome analyses were also stratified by length of follow-up after randomization (short term was less than 12 months, intermediate term was 12 to 24 months, and long term was greater than 24 months).

EPC reviewers used stratified analyses, visual inspection of forest plots arranged by effect size, and/or meta-regressions to examine the effect of a priori-specified primary sources of heterogeneity on effect size: study population, intervention type, overall intervention intensity (low was less than 30 minutes of total contact, medium was 30 to 360 minutes, and high was more than 360 minutes), number of intervention contacts, duration of intervention, length of follow-up, overall study quality, year of publication, country setting, type of control group, and population risk (including average age; percentage of persons who smoke or have hypertension, dyslipidemia, or diabetes; average systolic blood pressure; average low-density lipoprotein cholesterol level; average body mass index; and use of medications).

EPC reviewers assessed the presence of statistical heterogeneity among the studies using standard chi-square tests, and the magnitude of heterogeneity was estimated using the $I^2$ statistic. In instances of 10 or more studies, they formally assessed for publication bias and whether the distribution of the effect sizes was symmetrical with respect to the precision measure by using funnel plots and the Egger linear regression method. EPC reviewers did all analyses using Stata, version 11.2.

## Methods Used to Formulate the Recommendations

Balance Sheets

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

Table 1. U.S. Preventive Services Task Force Recommendation Grid*

| **Certainty of Net Benefit** | **Magnitude of Net Benefit** | | | |
|---|---|---|---|---|
| | **Substantial** | **Moderate** | **Small** | **Zero/Negative** |
| High | A | B | C | D |
| Moderate | B | B | C | D |
| Low | Insufficient | | | |

**A, B, C, D*, and *I (Insufficient)* represent the letter grades of recommendation or statement of insufficient evidence assigned by the USPSTF after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the USPSTF seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized, controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the USPSTF considers indirect evidence. To guide its selection of indirect evidence, the USPSTF constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

Do the studies have the appropriate research design to answer the key question(s)?
To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
How consistent are the results of the studies?
Are there additional factors that assist the USPSTF in drawing conclusions (e.g., presence or absence of dose–response effects, fit within a biologic model)?

The next step in the USPSTF process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the USPSTF's overall assessment of evidence was described as good, fair, or poor. The USPSTF realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term certainty will now be used to describe the USPSTF's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the USPSTF makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The USPSTF must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The USPSTF considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the USPSTF assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The USPSTF would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of the Recommendations" field). The USPSTF would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see "Availability of Companion Documents" field) summarizes the current terminology used by the USPSTF to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF, Guirguis-Blake J, LeFevre M, Harris R, Petitti D; U.S. Preventive Services Task Force. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147(12):871-875. [5 references].

## Rating Scheme for the Strength of the Recommendations

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

| Grade | Grade Definitions | Suggestions for Practice |
|---|---|---|
| A | The USPSTF recommends the service. There is high certainty that the net benefit is substantial. | Offer/provide this service. |
| B | The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. | Offer/provide this service. |
| C | The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small. | Offer/provide this service for selected patients depending on individual circumstances. |
| D | The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. | Discourage the use of this service. |
| I Statement | The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined. | Read the "Clinical Considerations" section of USPSTF Recommendation Statement (see the "Major Recommendations" field). If this service is offered, patients should understand the uncertainty about the balance of benefits and harms. |

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

| Level of Certainty | Description |
|---|---|
| High | The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies. |
| Moderate | The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:<br><br>The number, size, or quality of individual studies<br>Inconsistency of findings across individual studies<br>Limited generalizability of findings to routine primary care practice<br>Lack of coherence in the chain of evidence<br><br>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion. |
| Low | The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: |

| Level of Certainty | Description |
| --- | --- |
| | The limited number or size of studies<br>Important flaws in study design or methods<br>Inconsistency of findings across individual studies<br>Gaps in the chain of evidence<br>Findings not generalizable to routine primary care practice<br>A lack of information on important health outcomes<br><br>More information may allow an estimation of effects on health outcomes |

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

Peer Review. Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send a draft evidence review to 4 to 6 external experts and to Federal agencies and professional and disease-based health organizations with interests in the topic. The experts are asked to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. The draft evidence review is also posted on the USPSTF Web site for public comment. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the USPSTF in memo form. In this way, the USPSTF can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment among reviewers representing professional societies, voluntary organizations, and Federal agencies, as well as posted on the USPSTF Web site for public comment. These comments are discussed before the final recommendations are confirmed.

Response to Public Comment. A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from 13 May to 9 June 2014. Thirty-three comments were received. In response to these comments, the USPSTF clarified how this recommendation fits with related ones on healthy lifestyles and screening for obesity. It clarified the population under consideration throughout the recommendation statement and more explicitly defined the connections between the populations studied and the target population of the recommendation. The USPSTF also provided more detail on the evidence gap for CVD outcomes and added to the Research Needs and Gaps section. In addition, it added or updated several references and made other minor editorial changes.

Comparison with Guidelines from Other Groups. Recommendations for screening from the following groups were discussed: the American Heart Association (AHA), the American College of Sports Medicine, and the American Academy of Family Physicians (AAFP).

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

# Benefits/Harms of Implementing the Guideline Recommendations

## Potential Benefits

Benefits of Behavioral Counseling Interventions

The U.S. Preventive Services Task Force (USPSTF) found adequate evidence that intensive behavioral counseling interventions have moderate benefits for cardiovascular disease (CVD) risk in overweight or obese adults who are at increased risk for CVD, including decreases in blood pressure, lipid and fasting glucose levels, and body mass index (BMI) and increases in levels of physical activity. The reduction in glucose levels was large enough to decrease the incidence of a diabetes diagnosis. The USPSTF found inadequate direct evidence that intensive behavioral counseling interventions lead to decreases in mortality or CVD rates.

## Potential Harms

Harms of Behavioral Counseling Interventions

The U.S. Preventive Services Task Force (USPSTF) found adequate evidence that the harms of behavioral counseling interventions are small to none. None of the dietary intervention studies explicitly reported adverse events. Studies of physical activity interventions reported mostly minor adverse events, and intense physical activity was rarely associated with cardiovascular events.

# Qualifying Statements

## Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific clinical preventive services for patients without related signs or symptoms.
- It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.
- The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.
- Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

# Implementation of the Guideline

## Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to

implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the USPSTF will make all its products available through its Web site . The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access USPSTF materials and adapt them for their local needs. Online access to USPSTF products also opens up new possibilities for the appearance of the annual, pocket-size Guide to Clinical Preventive Services.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

See the Implementation section in the original guideline document for more information.

## Implementation Tools

Foreign Language Translations

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Staying Healthy

## IOM Domain

Effectiveness

Patient-centeredness

# Identifying Information and Availability

## Bibliographic Source(s)

U.S. Preventive Services Task Force. Behavioral counseling to promote a healthful diet and physical activity for cardiovascular disease prevention in adults with cardiovascular risk factors: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2014 Oct 21;161(8):587-93. [21 references] PubMed

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

1996 (revised 2014 Oct 21)

## Guideline Developer(s)

U.S. Preventive Services Task Force - Independent Expert Panel

## Guideline Developer Comment

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services or its agencies.

## Source(s) of Funding

The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that the Agency for Healthcare Research and Quality support the operations of the USPSTF.

## Guideline Committee

U.S. Preventive Services Task Force (USPSTF)

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**Members of the USPSTF at the time this recommendation was finalized. For a list of current Task Force members, go to http://www.uspreventiveservicestaskforce.org/Page/Name/our-members*.

## Financial Disclosures/Conflicts of Interest

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Disclosures

Dr. Gillman reports royalties from Cambridge University Press and UpToDate outside the submitted work. Authors not named here have disclosed no conflicts of interest. Authors followed the policy regarding conflicts of interest described at http://www.uspreventiveservicestaskforce.org/Page/Name/methods-and-processes. Disclosures can also be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M14-1796.

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Behavioral counseling in primary care to promote a healthy diet: recommendations and rationale. Am J Prev Med. 2003 Jan;24(1):93-100. [54 references]

This guideline meets NGC's 2013(revised) inclusion criteria.

## Guideline Availability

Electronic copies: Available from the Annals of Internal Medicine Web site.

## Availability of Companion Documents

The following are available:

Evidence Reviews:

> Lin JS, O'Connor EA, Evans CV, Senger CA, Rowland MG, Groom HC. Behavioral counseling to promote a healthy lifestyle for cardiovascular disease prevention in persons with cardiovascular risk factors: an evidence update for the U.S. Preventive Services Task Force. Evidence Report No. 113. AHRQ

Publication No. 13-05179-EF-1. Rockville (MD): Agency for Healthcare Research and Quality; 2014. 262 p.

Lin JS, O'Connor EA, Evans CV, Senger CA, Rowland MG, Groom HC. Behavioral counseling to promote a healthy lifestyle in persons with cardiovascular risk factors: a systematic review for the U.S. Preventive Services Task Force. Ann Intern Med, 2014 Oct 21;161(8):568-578.

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site .

Background Articles:

Barton MB et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. Ann Intern Med 2007;147:123-127.

Guirguis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. Ann Intern Med 2007;147:117-122.

Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med 2007;147:871-875.

Electronic copies: Available from the USPSTF Web site .

The following are also available:

Behavioral counseling to promote a healthful diet and physical activity for cardiovascular disease prevention in adults with cardiovascular risk factors. Clinical summary of U.S. Preventive Services Task Force recommendation. 2014 Aug. 1 p. Electronic copies: Available from the USPSTF Web site .

A continuing medical education (CME) activity is available from the Annals of Internal Medicine Web site .

The guide to clinical preventive services, 2014. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2014. 144 p. Electronic copies: Available from the AHRQ Web site . See the related QualityTool summary on the Health Care Innovations Exchange Web site .

The Electronic Preventive Services Selector (ePSS) is an application designed to provide primary care clinicians and health care teams timely decision support regarding appropriate screening, counseling, and preventive services for their patients. It is based on the current, evidence-based recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

## Patient Resources

The following are available:

Behavioral counseling to promote a healthful diet and physical activity for cardiovascular disease prevention in adults with cardiovascular risk factors. Understanding task force recommendations. U.S. Preventive Services Task Force. Consumer fact sheet. 2014 Aug. 4 p. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site .

Counseling to promote healthy diet and physical activity in adults with cardiovascular risk factors: U.S. Preventive Services Task Force recommendation statement. Summaries for patients. Ann Intern Med. 2014 Oct 21;161(8):I-36. Electronic copies: Available from the Annals of Internal Medicine Web site .

Women: stay healthy at any age. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 14-IP007-A. 2014 Mar. 5 p. Electronic copies: Available in English and Spanish from the AHRQ Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site .

Men: stay healthy at any age. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 14-IP006-A. 2014 Mar. 5 p. Electronic copies: Available in English and Spanish from the AHRQ Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

Women: stay healthy at 50+. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 14-IP002-A. 2014 Mar. 5 p. Electronic copies: Available in English and Spanish from the AHRQ Web site.

Men: stay healthy at 50+. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 14-IP009-A. 2014 Mar. 5 p. Electronic copies: Available in English and Spanish from the AHRQ Web site.

Print copies: Available from the AHRQ Publications Clearinghouse. For more information, go to http://www.ahrq.gov/research/publications/index.html or call 1-800-358-9295 (U.S. only).

Myhealthfinder is a tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at www.healthfinder.gov.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC Status

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